

### ***REMARKS***

New claims 56-73 have been added. Claims 49 and 50 have been cancelled. Claims 27, 31, 34, 38, 39, 40 and 48 have been amended. Upon entry of this paper, claims 27-48 and 51-73 will be pending and under consideration in this application.

Claims 27, 38, 40 and 48 have been amended to specify that the conjugate, which is "mobilizable," is "dried on said sorbent material" upstream of the test site. Support for the amendment may be found, for example, on page 7, lines 12-14 and page 11, line 28 - page 12, line 2 of the application as originally filed. Claim 31 has been amended to correct a grammatical error. Claims 34 and 38 have been amended to remove limitations that have been introduced into claims 27 and 38, respectively. Support for proposed new claims 56-73 may be found throughout the application and claims as originally filed. New independent claims 56 and 69, like the claims that issued in related U.S. Patent No. 6,485,982 B1, do not require the existence of a control site. Applicant believes that no new matter has been introduced by these amendments.

Applicant respectfully requests that the Examiner provide an initialed copy of the PTO-1449 form that was initially submitted to the Office on September 24, 2001 and then resubmitted on February 13, 2003. In addition, applications are in the process of preparing a Supplemental Information Disclosure Statement for submission to the Office.

The Supplemental Information Disclosure Statement will provide, in addition to other things, specific information about two patent infringement suits in which two or more of U.S. Patent Nos. 5,714,389, 5,989,921 and 6,485,982 have been asserted. The '389, '921 and '982 patents are related to the instant application. In a first suit, Armkel, LLC (the owner of the foregoing patents) filed a patent infringement action under the '389 and '921 patents against Pfizer, Inc. in U.S. Federal District Court for the District of New Jersey (Civil Action No. 02-4206 (MLC)). In this action, which the undersigned understands has since settled, Pfizer alleged non-infringement and invalidity of the '389 and '921 patents. In a second suit, Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. filed a patent infringement action under the '389, '921 and '982 patents against Acon Laboratories, Inc. in U.S. Federal District Court for the

District of Massachusetts (Civil Action No. 03 –11323 PBS). Armkel has been joined as a party in the lawsuit. In this action, Acon alleges non-infringement, invalidity and unenforceability of the ‘389, ‘921 and ‘982 patents.

In addition, the Supplemental Information Disclosure Statement will provide, in addition to other things, more specific information about a lawsuit filed by Quidel Corporation against Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH, Applied Biotech, Inc., and Armkel LLC in the U.S. District Court for the Southern District of California (Case No. 04 CV 0378 L(LSP)). In this Action, Quidel seeks a judicial determination and a declaration that certain patents, which include the ‘389, ‘921, and ‘982 patents, are not infringed by Quidel and that the patents are invalid and/or unenforceable.

Although applicants have filed a terminal disclaimer vis-à-vis the ‘921 patent, the Office is invited to review the ‘389 and ‘982 patents for potential double patenting issues. According to the outstanding Office Action, it appears that (i) the rejection under 35 U.S.C. 103(a) over Brown III (EP 217 403 A2) in view of Rosenstein has been withdrawn, and (ii) the rejection under 35 U.S.C. 103(a) over Brown III (EP 217 403 A2) in view of Ching has been withdrawn. The outstanding rejection is discussed in more detail below.

#### ***Rejection of Claims 27-55 Under 35 U.S.C. § 103(a)***

According to the outstanding Office Action, claims 27-55 presently stand rejected under 35 U.S.C. § 103(a) over Brown III *et al.*, U.S. Patent No. 4,916,056 (“Brown III”), in view of Ching *et al.*, U.S. Patent No. 5,120,643 (“Ching”). Applicant respectfully traverses this rejection in view of the following comments.

Applicant submits that the European counterpart of Brown III (namely EP 217 403 A2) has been discussed in detail in the responses of January 8, 2001, September 20, 2001, May 28, 2002, and February 13, 2003, the substance of which is incorporated here. The Office Action on page 2 suggests that, among other things, the device of Brown III comprises a test strip of a porous fiber matrix that “equates [to the claimed] sorbent material which defines a flow path for transporting

the liquid sample therealong from a sample contact region to a test site and a control site.”

Applicant respectfully disagrees with this statement for the reasons already of record.

Applicant submits that the Brown III device (see, for example, Figure 1 of Brown III) is based on a “flow-through” or “well-type” format where a liquid sample of interest passes through the thickness of a matrix rather than along the length of the matrix. In contrast, in the devices of the claimed invention, once a liquid sample of interest is applied to a sample contact region, the liquid sample traverses the test strip lengthwise by lateral flow from the sample contact region through a test site and optionally through a control site, located downstream of the sample contact region.

To the extent that the Office is relying on Figures 6 and 7 of Brown III to show a chromatographic device, Applicant submits that Figures 6 and 7 appear to have been introduced for the first time into application serial number 173,979, filed March 28, 1988, (the ‘979 application) which issued as U.S. Patent No. 4,916,056, the reference being applied in this rejection. The ‘979 application is a continuation-in-part of application serial number 831,013, filed February 18, 1986 (the ‘013 application), which does not appear to contain Figures 6 and 7 (see excerpt of the ‘013 application attached hereto as Exhibit A). Accordingly, Applicant believes that the earliest date attributable to Figures 6 and 7 of the ‘979 application is March 28, 1988. For the reasons discussed in more detail below, Applicant believes he was in possession of claimed invention prior to March 28, 1988 and, therefore, Figures 6 and 7 of the ‘979 application apparently are not be available as prior art against the claimed invention.

In addition, the Office Action acknowledges that Brown III fails to teach or suggest using as a detection system a colored particulate material, which is required by all the pending claims. The Office Action appears to rely on the teachings of Ching to make up for the deficiencies in Brown III. Applicants submit that Ching has an effective filing date of July 13, 1987.

However, Applicants have already made of record on January 8, 2001, a copy of a Declaration of David E. Charlton, Neal W. Miller and Margaret Mazzeo under 37 C.F.R. 1.131. The Declaration, which was filed in parent application U.S. Ser. No. 07/995,331 (which issued as the ‘389 patent) demonstrates that prior to March 27, 1987 the inventors were already in possession of lateral flow immunoassay test strip in which a conjugate comprising a specific

binder for the ligand and a colored particulate material (in that case gold sol-hCG specific antibody (b105<sub>15nm</sub>)) could flow along a test strip and be captured in a test site to provide a color visible to the unaided eye indicative of the presence of the ligand in the sample. Applicants submit that in this example, the conjugate was reconstituted in a liquid sample (either in the presence or absence of hCG) prior to its application to the test strip.

In addition, Applicants enclose a copy of a Showing Under 37 CFR 1.608(b) submitted to the Office during prosecution of related application U.S. Serial No. 08/465,675 (which issued as U.S. Patent No. 6,485,982 B1). The '675 application was the subject of Interference No. 104,148, in which priority of invention was ultimately awarded to the named inventor of the '675 application. A copy of the final decision was made of record in this case on February 13, 2003. The Showing Under 37 CFR 1.608(b) demonstrates that at least as of March 27, 1987, the inventor named on this application was already in possession of lateral flow immunoassay test strip in which a conjugate comprising a specific binder for the ligand and a colored particulate material could flow along a test strip and be captured in a test site to provide a color visible to the unaided eye indicative of the presence of the ligand in the sample. See, for example, Exhibit F of the Showing Under 37 CFR 1.608(b) together with the associated discussion in the Mazzeo and Charlton Declarations. Applicants submit that in Example F, for example, the mobilizable conjugate was dried on the sorbent material of the test strip. When liquid sample was applied to the test strip the conjugate was mobilized in the liquid sample and then moved along the test strip to the test site.

In view of the foregoing submissions, Applicant submits that he was in possession of his invention prior to July 13, 1987. As a result, Applicant submits that the reliance on Ching in the Office Action is improper. Applicant respectfully submits that Ching may not be relied upon to provide that which Brown III lacks.

In view of the foregoing, because Brown III fails to teach or suggest the claimed subject matter taken as a whole, and because Ching may not be used to make up for the deficiencies in Brown III, Applicant respectfully requests that the rejection of claims 27-55 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

**Conclusion**

In view of the foregoing, Applicant respectfully submits that the case is in condition for immediate allowance. Early favorable action is respectfully solicited.

Respectfully submitted,



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